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8 PATENT
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10 PORTABLE GAS POWERED POSITIVE
11 PRESSURE BREATHING APPARATUS AND METHOD

12 RELATED APPLICATION

13 This application is a continuation-in-part of
14 provisional application no. 60/288,713, filed May 7, 2001.

15 FIELD OF THE INVENTION

16 The present invention relates to an apparatus and
17 method for use in respiratory therapy and more
18 particularly to a portable system for use in supplying a
19 continuous and/or dual level positive airway pressure
20 treatment to a patient in respiratory distress and
21 method. As used herein the term oxygen or O₂ includes
22 air and oxygen enriched air as well as purified O₂.

23 BACKGROUND OF THE INVENTION

24 Individual's suffering from pulmonary edema, i.e.,
25 the effusion of serious fluid into the lungs, and certain
26 other respiratory ailments are generally treated by
27 forcing breathable gas, normally oxygen (O₂) into the
28 lungs and maintaining the pressure within the lungs at a
29 level, e.g., 1 to 20 centimeters of water above
30 atmospheric. The O₂ can be supplied directly to the
31 lungs through an endotracheal tube, one end of which is
32 inserted into the lungs through the individual's mouth,
33 i.e., intubation. The invasive technique of intubation

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~~intubation~~
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requires considerable skill and can cause serious injury to the patient. Also, the recovery time of intubated patients may be considerable.

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Alternatively, a patient may be fitted with a breathing appliance such as a face mask which is equipped with an inlet for receiving oxygen under pressure and an inhalation/exhalation valve for exhausting exhaled air to the atmosphere. The respiratory departments of many hospitals have relatively sophisticated equipment for supplying oxygen at continuous and/ or dual level pressure to such appliances. However, such equipment is neither readily portable nor simple to operate and often is not available in emergency rooms.

Portable systems are currently available for use in emergency rooms by nurses and in the field by emergency rescue personnel, e.g., paramedics, for the continuous positive airway pressure ("CPAP") procedure. However, such portable systems conventionally rely on a spring loaded check valve located in or near the face mask to set the maximum pressure in the mask. The check valve serves to bypass the oxygen stream to the atmosphere during the patient's exhalation phase. The flow rate is normally adjusted to accommodate a patient's peak inhalation flow rate, e.g., 75 to 100 liters per minute (l/m). A patient typically inhales around 10 to 12 l/m with each exhalation phase exceeding the time duration of the inhalation phase by a factor of two or more.

As a result, currently available portable systems for use by emergency rescue personnel consume oxygen at a high rate stemming from the fact that they are continuous flow devices that must cater to high demand and waste O₂ during the longer expiration phase of the

1 respiratory cycle. Also, this high flow rate creates
2 unwanted additional expiratory work for the patient.

3 In a normal respiratory cycle the torso muscles act
4 to expand the lungs and thus draw air into them during
5 the inhalation cycle. Exhalation is accomplished by the
6 muscles relaxing and the elastic recoil of the chest
7 forcing air from the lungs. During positive pressure
8 breathing the muscle action is reversed so that air
9 enters the lungs under pressure and exhalation requires
10 forceful action by the abdominal muscles. Thus,
11 exhalation under conventional CPAP treatment involves a
12 significant amount of exertion for the patient.

13 The shock to a patient being suddenly confronted
14 with a significant amount of pressure in his or her
15 airway, e.g., 10 to 20 cm H₂O during
16 inhalation/exhalation is another disadvantage of the
17 currently available portable CPAP systems.

18 U.S. Patent No. 5,148,802 and related Patent Nos.
19 5,433,193 and 5,632,269, while not directed to portable
20 CPAP systems for use by emergency rescue personnel,
21 disclose a sophisticated system ("'802 system") employing
22 the CPAP treatment for individuals suffering from sleep
23 apnea. The '802 system, which is designed to keep the
24 individual's airway continuously open during sleep,
25 employs a sensitive flow sensor and complicated
26 electronic circuitry to determine when the user is
27 exhaling and lowers the applied pressure during the
28 expiratory phase.

29 The '802 system is expensive and, as with many
30 complicated electronic devices, would be subject to
31 failure if mishandled.

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1 There is a need for a simple, inexpensive, reliable,
2 portable and rugged apparatus which can be used by
3 emergency rescue personnel whether in the field or in
4 emergency rooms to ventilate a patient's lungs with
5 oxygen under continuous positive airway pressure.

6 SUMMARY OF THE INVENTION

7 A continuous positive airway pressure apparatus or
8 system for supplying O₂ from a pressurized source to an
9 individual's breathing appliance in accordance with the
10 present invention includes a demand pressure regulator
11 for supplying O₂ to the patient's breathing appliance,
12 e.g., a face mask, only when demanded. The system
13 includes a demand valve with a supply inlet port adapted
14 to be connected to the pressurized source, an outlet port
15 adapted to be connected to the appliance's inlet, a
16 reference chamber and a valve assembly responsive to the
17 reference chamber/appliance inlet pressure differential
18 for connecting and disconnecting the inlet port to and
19 from the outlet port.

20 The system further includes at least one manually
21 adjustable back pressure regulator connected to the
22 pressurized source and the reference chamber for setting
23 the pressure in the reference chamber (and inlet to the
24 breathing appliance) at a selected level above
25 atmospheric pressure.

26 Optionally the system may include an additional
27 manually adjustable or fixed back pressure regulator with
28 one regulator controlling the back pressure during
29 inhalation and the other controlling the back pressure
30 during exhalation and connected to the reference chamber
31 to act in parallel or series to create bi-level
32 pressures. The system may also include a nebulizer

1 outlet for supplying low flow O₂ to a nebulizer during
2 the patient's inhalation phase. In addition, a preferred
3 patient valve to be attached to or incorporated in the
4 breathing appliance may be used with the adjustable back
5 pressure regulator/demand valve. The improved patient
6 valve maintains the pressure in the patient's airway very
7 close to the selected back pressure during inhalation and
8 exhalation regardless of the magnitude of the selected
9 pressure level. The improved patient valve is
10 particularly advantageous where the reference back
11 pressure remains the same during the entire breathing
12 cycle.

13 A method of treating a patient suffering from
14 pulmonary edema or other respiratory ailment in
15 accordance with the present invention includes the
16 following steps:

- 17 a) securing a breathing appliance to the patient's
18 airway with the appliance having an inlet and an
19 inhalation/exhalation valve to allow breathable gas
20 passing through the inlet to enter the patient's lungs
21 during the inhalation phase and allow expired air to exit
22 to atmosphere during the exhalation phase;
- 23 b) providing a pressurized source of O₂;
- 24 c) providing at least one reference pressure at a
25 selected value above atmospheric pressure;
- 26 d) monitoring the pressure at the appliance inlet;
- 27 e) comparing the appliance inlet pressure with the
28 reference pressure;
- 29 f) connecting and disconnecting the pressurized
30 source to the mask inlet when the inlet pressure falls
31 below and rises to the reference pressure, respectively;
32 and

1 g) varying the selected value of the reference
2 pressure during the treatment.

3 The construction and operation of the present
4 invention may best be understood by reference to the
5 following description taken in conjunction with the
6 appended drawings, wherein like components are designated
7 with the same reference numeral in the several figures.

8 BRIEF DESCRIPTION OF THE DRAWINGS

9 Fig. 1 is a system schematic of the present
10 invention in an assembled state with a face mask and
11 nebulizer;

12 Fig. 2 is a front view of a housing in which the
13 various components of the invention are mounted;

14 Fig. 3 is a cross-sectional view of the components
15 demand valve within the housing including a pressure
16 regulator, pressure gauge, a maximum pressure relief
17 valve and an anti-suffocation relief valve;

18 Fig. 4 is a cross-sectional view of the demand valve
19 and the two relief valves;

20 Fig. 5 is a cross-sectional view of the pressure
21 regulator;

22 Fig. 6 is a schematic cross-sectional view of a
23 nebulizer which may be used with the invention;

24 Fig. 7 is a cross-sectional schematic view of the
25 demand valve and pressure regulator showing the demand
26 valve as configured during a patient's exhalation phase;

27 Fig. 8 is a cross-sectional schematic view of the
28 demand valve and pressure regulator as configured during
29 the inhalation phase;

30 Fig. 9 is a pressure diagram illustrating how the
31 pressure at various points in the system changes with the
32 flow rate;

1 Fig. 10 and 11 are cross-sectional schematic views
2 of the nebulizer valve configured in the exhalation and
3 inhalation modes, respectively;

4 Fig. 12 is a pressure diagram showing pressures at
5 several points in the system relevant to the operation of
6 the nebulizer valve;

7 Figs. 13 and 14 are schematic cross-sectional views
8 of a bi-level controlled demand valve functioning with
9 two independently adjustable pressure regulators in the
10 exhalation and inhalation modes, respectively;

11 Figs. 15 and 16 are schematic cross-sectional views
12 of a bi-level controlled demand valve with only one field
13 adjustable pressure regulator configured in the
14 exhalation and inhalation modes, respectively;

15 Figs. 17 and 18 are schematic cross-sectional views
16 of an improved face mask valve for use with the invention
17 as configured in the exhalation and inhalation modes,
18 respectively; and

19 Fig. 19 is a top plan view of the face mask valve
20 showing the angle through which the atmospheric outlet
21 stub can swivel around the housing.

22 DESCRIPTION OF THE PREFERRED EMBODIMENT

23 ~~Referring now to the drawings, and particularly to~~
24 ~~the system schematic of the invention shown in Fig. 1, a~~
25 ~~demand oxygen regulator 10 is powered by a pressurized~~
26 ~~O₂ source 11 through an inlet port 12. An adjustable~~
27 ~~back pressure regulator 14 receives pressurized O₂ on~~
28 ~~conduit or line 15 through a flow restrictor 16. A~~
29 ~~pressure gauge 18 provides a measure of the pressure~~
30 ~~within the outlet 22 of a demand oxygen regulator 10. O₂,~~
31 ~~at the desired pressure, is supplied from the demand~~
32 ~~oxygen regulator outlet 22, to a mask 20, via an inlet~~

1 26a of a balanced inhalation/exhalation patient valve 26
2 attached to or incorporated into the mask, and a
3 conventional hose or tube 25. The inlet 26a is
4 hereinafter sometimes referred to as the breathing
5 appliance inlet.

6 Low flow O₂ is also supplied to a nebulizer 26 from
7 ^{as} a nebulizer outlet 28 and a nebulizer shut off valve 30
8 (incorporated in the pressure regulator as will be
9 described in more detail). The output of the nebulizer
10 is combined with the O₂ delivered to the patient's mask
11 through the tube 25 in a conventional manner.

12 Referring now to Figs. 2 and 3 the demand oxygen
13 regulator 10, back pressure regulator 14 and pressure
14 gauge 18 are mounted within a housing 32. The pressure
15 gauge 18 is placed in fluid communication with the outlet
16 22 via line 31. Line 33 connects the outlet of a
17 nebulizer valve (to be described) to the outlet 28. Line
18 34 connects a supply inlet 36 of the demand regulator 10
19 to the O₂ inlet nipple 12.

20 Referring now to Fig. 4 the demand O₂ regulator 10
21 includes a demand valve 40, a maximum pressure relief
22 valve 38 and an anti-suffocation valve 39. The valves 38
23 and 39 are mounted in a housing 42 which is secured to
24 the demand valve housing by bolts, for example. The
25 upstream interior section of the housing 41 forms the
26 outlet port 46 for the demand valve, as will be discussed
27 in more detail in connection with Figs. 7 and 8.

28 The relief and anti-suffocation valves are
29 conventional poppet valves with the valves 38 and 39
30 opening when the pressure in demand valve outlet 46
31 reaches a preset maximum value or falls below
32 atmospheric pressure, respectively. The demand valve 40

1 includes the supply inlet 36, the outlet port 46, a
2 reference pressure inlet 48 and a nebulizer valve outlet
3 50. The internal components of the demand valve 40 will
4 be described in conjunction with Figs. 7 and 8.

5 Referring now to Fig. 5 the back pressure regulator
6 valve ¹⁵ ~~14~~ is a conventional poppet valve with a top
7 housing section 14a, a lower housing section 14b, an
8 inlet 14c connected to the pressurized source via
9 restrictor 16 (Fig. 3), an atmospheric outlet port 14d,
10 and a valve plate 14e which is biased against seat 14f by
11 spring 14g. An axially moveable plunger 14h responds to
12 the rotation of knob 14i to adjust the compressive force
13 applied by the spring to the valve plate 14e which in
14 turn restricts the flow in line 15 from the O₂ source 11
15 to adjust the back pressure at inlet 14c, e.g., 1 to 20
16 cm H₂O to establish the desired reference pressure in
17 line 15a to the demand valve as will be described in
18 connection with Figs. 7 and 8.

19 The ^{air} ~~nebulizer~~ 26, as shown in Fig. 6, includes a
20 container for liquid medication 26b. Pressurized O₂
21 leaving nozzle 26c educts vaporized medication into
22 stream 26d which enters the tube 25 adjacent the face
23 mask during the inhalation phase of the patient's
24 breathing cycle.

25 Referring now to Figs. 7 and 8 the demand valve 40
26 includes a main or first diaphragm valve 52 in which
27 first and second chambers 52a and 52b are disposed on
28 opposite sides of a moveable diaphragm 52c. The
29 diaphragm 52c closes against a seat 52d disconnecting
30 pressurized passage 36a and the inlet 30 from passage 46a
31 when the pressures in chambers 52a and 52b are equal due
32 to the greater exposed surface area on the top versus the

1 bottom side of the diaphragm. A second diaphragm valve
2 54, which controls the operation of the main valve, has
3 a pressure reference chamber 54a (open to the reference
4 pressure inlet 48) and a second chamber 54b disposed on
5 opposite sides of a sensing diaphragm 54c. The second
6 valve also includes a normally closed spring biased
7 paddle assembly comprising a pivotal arm 54d biased by
8 spring 54e to normally close pilot valve orifice 54f.

9 The nebulizer (third) valve 30 includes chambers 30a
10 and 30b, disposed on opposite sides of diaphragm 30c.
11 The diaphragm 30c serves to close the nebulizer valve
12 outlet 50 when the pressure in chambers 30a and 30b are
13 equal due to the area of the diaphragm exposed to chamber
14 30b being greater than the area exposed to chamber 30a.
15 A passageway 36b connects the chamber 30a to the inlet 36
16 as illustrated.

17 *NOTE* ~~A passageway 36c connects the upper chamber 52a, the~~
18 ~~pilot valve orifice 54f and inner chamber 30a to the~~
19 ~~pressurized source via a flow restrictor 36d. Passageway~~
20 ~~46e connects the lower chamber 54b of valve 54 to an~~
21 ~~outlet chamber 46c of the demand valve, which chamber~~
22 ~~extends above the outlet port and circumferentially~~
23 ~~around a nozzle 46b.~~

24 In the operation of the system of Figs. 7 and 8 the
25 pressure regulator 14, having been preset to the desired
26 positive mask pressure, provides that reference pressure
27 e.g., 1 to 20 cm H₂O via line 15a to the reference
28 chamber 54a. In the exhalation mode the main valve 52 is
29 closed disconnecting the passage 46a and nozzle 46b from
30 the inlet. When the patient begins to inhale the low
31 pressure in the mask inlet, demand valve outlet port 46
32 and outlet chamber 46c falls slightly below the reference

1 pressure in chamber 54a, and as a result, the diaphragm
2 54c moves downwardly to engage the paddle valve assembly
3 arm 54d, and lift it off of the pilot valve seat 54f.
4 This bleeds the high pressure O₂ in line 36c to the lower
5 pressure chamber 54b and the outlet port.

6 The flow restrictor 36d allows the pressure in
7 chamber 52a to drop below the pressure in inlet passage
8 36a a sufficient amount to cause the main valve 52 to
9 open as is illustrated in Fig. 8, to initiate the
10 inhalation mode. The main valve will remain open as long
11 as the pressure in the mask inlet and outlet chamber 46c
12 remains below the reference pressure. When the patient
13 initiates his or her exhalation phase the pressure in the
14 outlet port 46 and chamber 54b will rise to the reference
15 pressure thereby releasing the diaphragm 54c from the
16 paddle wheel arm 54d and allowing the spring to close the
17 pilot valve 54f. This action immediately allows the
18 pressure in the line 36c and chambers 52a to rise to a
19 level sufficient to close the main valve as is shown in
20 Fig. 7.

21 In this manner O₂ is supplied to the patient only on
22 demand and at a pressure level which can be determined by
23 the operator prior to and/or during the treatment. This
24 results in a considerable saving of O₂ over the O₂
25 consumed by the conventional portable CPAP systems.

26 There is a pressure drop across the hose or tubing
27 which connects the mask inlet to the demand valve outlet
28 port as well as in the mask valve itself, which pressure
29 drop is proportional to the O₂ flow rate. The demand
30 valve outlet chamber 46c and nozzle 46b compensate for
31 this loss as is illustrated in Fig. 9. The pressure in
32 outlet chamber 46c is decreased by flow through the

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1 nozzle 46b, i.e., aspiration effect, in proportion to the
2 flow rate. The nozzle and outlet chamber are designed, as
3 illustrated in Fig. 9, to cause an increase in the
4 pressure in the demand valve outlet port 46 (and decrease
5 the pressure in the chamber 46c) which pressure increase
6 mirrors the pressure drop across the tubing and mask
7 valve as a function of flow rate. In this manner the
8 resulting mask pressure is maintained almost equal to the
9 adjusted reference pressure regardless of flow rate.

10 It is to be noted that the term pressure
11 representative of the breathing appliance inlet pressure
12 includes the pressure in the mask inlet and may include
13 the demand valve outlet port pressure where the pressure
14 loss in the tubing and/or patient valve is not
15 compensated for.

16 *TO SET UP* ~~The operation of the nebulizer valve 30 may best be~~
17 ~~understood by reference to Figs. 10-12. The inlet~~
18 ~~pressure, e.g., 50 psi, is applied to both chambers 30a~~
19 ~~and 30b of the third valve 30 in the static condition,~~
20 ~~i.e., pilot valve 54f and main valve 52 are closed. In~~
21 ~~the absence of O₂ flow through the main valve 52, e.g.,~~
22 ~~exhalation mode, the diaphragm 30c closes the nebulizer~~
23 ~~outlet 50 due to the unequal areas of the diaphragm~~
24 ~~exposed to the opposing chambers. When the pilot and~~
25 ~~main valves open, at the initiation of inhalation, the~~
26 ~~pressure (P1) in passageway 36c decreases immediately, as~~
27 ~~explained earlier, allowing the diaphragm 30c to open the~~
28 ~~nebulizer valve. This allows O₂ to flow through~~
29 ~~restrictor 30d (Fig. 10), into the nebulizer outlet 50,~~
30 ~~through restrictor 54 to the nebulizer nozzle 26.~~

31 Fig. 12 is a pressure diagram showing the pressure
32 at various points associated with the nebulizer during

1 inhalation and exhalation. Curves P1, P2 and P3
2 represent the pressure in line 36b, chambers 30b and
3 outlet 50, respectively during the inhalation and
4 exhalation modes as indicated.

5 A bi-level pressure regulator is illustrated in
6 Figs. 13 and 14 configured in the exhalation and
7 inhalation modes, respectively. An additional adjustable
8 back pressure regulator 14' and an inhalation/exhalation
9 responsive or selector valve 56 enables an operator to
10 adjust separate reference pressures for the exhalation
11 and inhalation phases of the breathing cycle. The valve
12 56 includes chambers 56a and 56b disposed on opposite
13 sides of a diaphragm 56c. The valve has outlet ports 56d
14 and 56e connected to the inlets 14c and 14c' of the
15 pressure regulators 14 and 14' as shown. A first inlet
16 port 56f is connected to line 15 and the reference
17 chamber 54a. A second inlet 56g is connected to
18 nebulizer outlet, via line 58.

19 *In the exhalation mode the pressure P3 (Fig. 12) in*
20 ~~line 58~~ *and chamber 56a is low and the valve 56 is open*
21 *connecting the line 15 and reference chamber to the*
22 *inlets of both pressure regulators. As a result the*
23 *reference pressure is dictated by the pressure regulator*
24 *having the lowest pressure setting, i.e., valve 14'.* In
25 *the inhalation mode, with the main valve open, the*
26 *pressure P3 in line 58 rises to force diaphragm 56c*
27 *against the seat surrounding the outlet 56e thereby*
28 *connecting only the inlet of the regulator 14 to the line*
29 *15 and the reference chamber. In this mode the reference*
30 *pressure is set by the regulator 14.*

31 Where the system is equipped with two independently
32 adjustable pressure regulators, as in Figs. 13 and 14,

1 the exhalation pressure experienced by the patient may be
2 adjusted to any level equal to or below (down to
3 atmospheric pressure) the inhalation pressure. Thus, a
4 patient's effort required to exhale may be considerably
5 reduced.

6 An alternative embodiment of a bi-level system is
7 illustrated in Figs. 15 and 16. This system functions in
8 similar manner with one of the pressure regulators, i.e.,
9 regulator 55 being preadjusted at the factory to connect
10 its input 55a to atmosphere via output 55b at a selected
11 pressure, e.g., 10 cm H₂O. A selector diaphragm valve 57
12 connects the outlet 14d of pressure regulator 14 to
13 atmosphere via line 59a, inlet port 57a, and outlet port
14 57b during the exhalation mode as is illustrated in Fig.
15 15. During the inhalation mode (Fig. 16) the rise in
16 pressure in line 58 (P3, Fig. 12) transmitted through
17 inlet orifice 57c causes diaphragm 57d to close outlet
18 57b, connecting the outlet of pressure regulator 14 to
19 the inlet 55a of pressure regulator 55. Thus, the
20 inhalation pressure will always be a fixed pressure
21 (e.g., 10 cm H₂O) above the exhalation pressure as set by
22 the manually adjustable pressure regulator 14.

23 It is to be noted that the term manually adjustable
24 as used herein is not to be interpreted as limited to a
25 rotatable knob arrangement. The term is to be interpreted
26 to include any arrangement which allows the operator to
27 readily change the reference pressure before and during
28 a treatment.

29 Figs. 17 and 18 illustrate a cross-sectional
30 schematic view of an improved patient valve arrangement
31 58 for use with or incorporation into a patient's face
32 mask in accordance with this invention. The patient

1 valve 58 comprises an inlet passage 58a terminating in an
2 inhalation check valve 58b that acts to permit flow from
3 the inlet 58a to an inlet/outlet chamber 58c which in
4 turn is adapted to be placed in fluid communication with
5 the patient's airway via a face mask etc. A passage 58d
6 conducts gas (O_2) from the inlet to a diaphragm chamber
7 58e. This chamber is formed by the upper surface of
8 diaphragm 58f secured at its periphery to the inner wall
9 of valve housing 58j, the upper top central surface 58g
10 of a circular valve member 58h and the interior of an
11 upper section 58i of the generally cylindrically shaped
12 valve housing 58j as illustrated. The valve member 58h
13 is secured to and suspended by the radially inner portion
14 of the diaphragm. This chamber 58e acts to provide
15 pneumatic damping and pressure balance to the operation
16 of valve member 58h. When the patient exhales, the
17 pressure in the inlet/outlet chamber 58c rises above the
18 pressure in the inlet 58a. This causes check valve 58b
19 to close, allowing diaphragm 58f and valve member 58h to
20 move upwardly lifting the valve member off of its annular
21 seat 58k formed at the upper (terminal) end of the
22 inlet/outlet chamber 56c. Flow is then directed through
23 an exhaust casing 58l which surrounds the valve seat and
24 thence to exhaust port 58m and to atmosphere via passage
25 58n. The exhaust port, formed in exhaust casing 58l,
26 which is rotatable through an angle of about 300° with
27 respect to the valve housing 58j allows the patient's
28 expired air to be directed as desired.

29 An important design feature of the valve is the
30 balancing of the effective areas of the diaphragm 58f
31 (and upper surface 58g of the valve member) and the valve
32 seat area 58k. The effective area of the diaphragm has

1 a diameter d₁ and the median diameter of the valve seat
2 is d₂. These two diameters are preferably about equal.
3 This feature allows the exhalation pressure to be
4 maintained at a level almost equal to the inhalation
5 pressure in inlet 58a, regardless of the positive
6 pressure level.

7 There has thus been described a novel apparatus or
8 system for supplying breathable gas such as O₂ under the
9 continuous positive airway pressure technique which is
10 portable, rugged, simple to use and very conservative in
11 its use of O₂. Various modifications and additions to
12 the disclosed apparatus will occur to those skilled in
13 the art without involving any departing from the spirit
14 and scope of the invention as defined in the appended
15 claims.

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